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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,699	05/08/2002	Dan L. Eaton	P3230R1C001-168	9949

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EXAMINER	
FIELD, TAMMY K	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/063,699	EATON ET AL.	
	Examiner	Art Unit	
	Tammy K. Field	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *September 17, 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☒ Claim(s) *1-20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *September 17, 2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Non-Final Action

1. Claims 1-20 are pending and under consideration.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

3. This application lacks a paper copy of the sequence listing, as required by 37 C.F.R. §1. 821(c). Applicants are required to submit such in response to this office action, and are further reminded that a statement in compliance with 37 C.F.R. §1. 821(f) must be made at such time.

4. The use of the trademarks TWEEN™, PLURONICS™, MATCHMAKER™, and BaculoGold™ has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Appropriate correction is required.

Information Disclosure Statement

5. The information disclosure statement, filed 9/17/2002, has been considered. The BLAST results demonstrate that applicants are aware of nucleic acids with identity/homology to the one claimed herein. However, as the BLAST results do not give sufficient identifying information, the Examiner cannot determine if said sequences constitute prior art.

Claim Objections

6. Claims 1-20 are objected to because of the following informalities: Claims should not recite Figures. (MPEP 2173.05(s)). Appropriate correction is required.

Priority

7. This invention is found to lack utility, see rejections below. Accordingly, priority is merited only to the instant filing date, 5/8/2002 and will therefore be used for purposes of prior art. Should the applicant disagree with the examiner's factual determination above, it is incumbent upon the applicant to provide the serial number and specific page number(s) of any parent application filed prior to the date recited above which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession of and fully enabled for prior to that date.

Rejections under 35 U.S.C. §101 and §112:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1-20 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility.

The specification discloses a protein designated PRO1411, and nucleic acid encoding such. There is no discussion of the structure of the protein encoded by the claimed nucleic acids, nor disclosure of any relationship between such structure and a purported function. There is no disclosure of any disease or condition in any way related to the nucleic acids that are claimed, nor disclosure of any diagnostic or analytical assay that could be performed using the claimed nucleic acids.

The specification discloses that the claimed nucleic acids **may/can be** (emphasis added) used as hybridization probes (page 89), to generate either transgenic animals or "knock out" animals (page 90), and as chromosomal markers (page 98). None of these assertions is specific, as none makes use of any specific property of the claimed nucleic acids, but rather could be asserted as a use for any nucleic acid that encodes any protein.

Utility must be in readily available form. In Brenner v. Manson, 148 U.S.P.Q. 689 (Sup. Ct,.1966), a process of producing a novel compound that was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be useful because the compound produced thereby was potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The instant claims are drawn to a polynucleotide encoding a protein which has undetermined function or biological significance. Until some actual and specific activity can be attributed to the protein identified in the specification as PRO295 protein or the polynucleotides encoding it, the claimed invention is incomplete. Merely using the polynucleotides to determine the properties of the encoded protein does not constitute a patentable utility.

It is further noted that PRO1411 is disclosed as having given positive results in a single assay, the stimulation of TNF-α release in human blood, assay 128, at page 139. In that assay, it is stated that the PRO polypeptide was added to human blood, and then tested for the presence of

TNFα by ELISA assay. The specification disclose that "A positive in the assay is a higher amount of TNF-α in the PRO polypeptide treated samples as compared to the negative control samples." This assay is not considered to impart utility to the protein PRO1411, nor to the nucleic acids that encode it. The reason for this determination is that no results are presented, and the standard disclosed, "a higher amount", is not considered to be an acceptable standard in the scientific community. It is well accepted in experimental science that, in order for a result to be positive, it must be *significantly* different from the control value, not "a higher amount" as reported in the specification. In this case, it is further noted that the protein (TNF-α) was detected using an extremely sensitive immunoassay, such that "a higher amount" does not indicate anything more than that a trace amount of TNF-α was present. Therefore, the assertion that the protein could be used "where stimulation of the release of TNF-α would be desired and for the therapeutic treatment of conditions wherein enhanced TNF-α release would be beneficial" is not substantial. The Examiner further notes that she is unaware of *any* condition in which stimulation of TNF-α release in the bloodstream would be desirable, even if, *in arguendo*, significant amounts of the cytokine were produced. Accordingly, the tacit assertion that PRO1411 stimulates TNF-α release from blood cells does not meet the requirements of 35 U.S.C. § 101, as the assertion of utility would not be considered substantial by a person of ordinary skill in the art.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-20 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

10. Claims 1-6, 8-10, and 14-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to polynucleotides having at least 80%, 85%, 90%, 95% or 99% sequence identity with a particular disclosed sequence, or that merely hybridize to a disclosed sequence. The claims do not require that the claimed polynucleotide encode a particular protein, nor that any protein encoded thereby possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polynucleotides that are defined only by sequence identity. Further, numerous claims define such in relation to the 'extracellular domain' of the protein or "its associated signal sequence", for which there is no description in the specification. The structure of the putative PRO1411 peptide is not discussed in the specification; there is no disclosure that the protein is expected to be a transmembrane protein, nor of any extracellular domain, nor of any signal sequence.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, nucleic acids comprising the sequence set forth in SEQ ID NO: 51, or fragments thereof sufficiently long enough to be used as hybridization probes but not the full breadth of the claims meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

11. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The deposit of biological organisms is considered by the Examiner to be necessary for enablement of the current invention (see 37 C.F.R.§1.808(a)). Examiner acknowledges the deposit of organisms under accession number ATCC 203245 under terms of the Budapest Treaty on International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure in partial compliance with this requirement. However, in order to be fully compliant with the requirement, applicants must state that the deposit will be maintained for a term of at lest 30 years *and at least five (5) years after the most recent request for the furnishing of a sample of the deposit was received by the depository*. See 37 C.F.R.§1.806.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims that recite "the extracellular domain" of the protein are indefinite as no extracellular domain has been described. Therefore, the metes and bounds of the claims cannot be determined. For example, see Claim 1, parts (c) and (d). Further, if the protein had an extracellular domain, the recitation of "the extracellular domain", "...lacking its associated signal sequence" (claim 1, part (d), for example) is indefinite as a signal sequence is not generally considered to be part of an extracellular domain, as signal sequences are cleaved from said domains in the process of secretion from the cell. Also, the recitation that the polypeptide lacks "its associated signal peptide" is indefinite, as no signal peptide has been described. Finally, "CHO" is an indefinite abbreviation recited in Claim 20.

Claims that recite that the claimed nucleic acid "hybridizes to" another sequence, such as claim 14, are indefinite as there is no limiting definition of such in the specification, and the metes and bounds of that which will hybridize are dependent upon the conditions under which the hybridization is performed. As the metes and bounds of what will hybridize to a given sequence are entirely dependent upon the conditions of hybridization and washing, the metes and bounds of the claims cannot be determined. With respect to claim 15, although the further limitation that the hybridization conditions are "stringent" is introduced, the term "stringent conditions" is also a relative term, and the metes and bounds of the claim cannot be determined.

The remaining claims are rejected for depending from an indefinite claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Baker, K.P. *et al.* (WO 01/68848 A2 published 20 Sept. 2001 with an earlier filing date of 1 Dec. 2000).

The claims are drawn to nucleic acids having at least 80%, 85%, 90%, 95%, 99% nucleic acid sequence identity to the nucleic acid sequence of the nucleic acid or the full-length coding sequence of the cDNA, also identified as DNA59212-1627 and ATCC accession number 2033245, shown in Figure 51 (SEQ ID NO: 51).

Baker, K.P. *et al.* teach a nucleic acid of SEQ ID NO: 201 that is 100 % identical to the bases 1-1734 of instant SEQ ID NO: 51 (see GenCore version 5.1.6 ©1992-2004, Result Number 4, Summary (page 1) and alignment (pages 4-6). Baker, K.P. *et al.* further teach the nucleic acid of SEQ ID NO: 201 encodes the polypeptide of SEQ ID NO: 202 at page 17 (see Figures 201 and 202). Baker, K.P. *et al.* also teach full length native sequence nucleotide sequences or portions thereof may be used as hybridization probes at page 78, lines 36-37. Vectors, host cells, *i.e. E. coli*, and expression vectors are also disclosed (see abstract).

As to claim(s) 7-10 containing recitations of the intended use of the claimed product(s), the purpose(s) must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art

structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Thus, Baker, K.P. *et al.* anticipates the instantly claimed invention.

14. Claims 1-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Baker, K.P. *et al.* (U.S. PreGrant Publication published 6 Feb. 2003 with an earlier filing date of 18 Sept. 2000).

The claims are drawn to nucleic acids having at least 80%, 85%, 90%, 95%, 99% nucleic acid sequence identity to the nucleic acid sequence of the nucleic acid or the full-length coding sequence of the cDNA, also identified as DNA59212-1627 and ATCC accession number 2033245, shown in Figure 51 (SEQ ID NO: 51).

Baker, K.P. *et al.* teach a nucleic sequence SEQ ID NO: 201 that is 100 % identical to the bases 1-1734 of instant SEQ ID NO: 51 at Fig. 201 and further designating as a nucleotide sequence of a native sequence PRO1411 cDNA designated as DNA59212-1627, page 10 [0227] (also see GenCore © 1993-2004, Result Number 50 and alignment, pages 98-100). Baker, K.P. *et al.* further teach the nucleic acid of SEQ ID NO: 201 encodes the amino acid sequence of SEQ ID NO: 202 at page 17 (see Figures 201 and 202). Baker, K.P. *et al.* also teach PRO variant polynucleotides are nucleic acid molecules that encode an active PRO polypeptide and which are capable of hybridizing to nucleotide sequences encoding a full-length PRO polypeptide at page 26, [0659]. Vectors, host cells, *i.e. E. coli*, and expression vectors are also disclosed (see abstract).

As to claim(s) 7-10 containing recitations of the intended use of the claimed product(s), the purpose(s) must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Thus, Baker, K.P. *et al.* anticipates the instantly claimed invention.

15. Since the office does not have the facilities for examining and comparing applicants' detection and diagnosis methods with the methods disclosed in the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed method and the methods of the prior art (*i.e.* that the methods of the prior art does not possess the same material structural and functional characteristics of the claimed methods). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald *et al.*, 205 USPQ 594.

Status of Claims

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammy K. Field whose telephone number is (571) 272-0856. The examiner can normally be reached on Monday-Friday from 7am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached at (571) 272- 0864.

Papers relating to this application may be submitted to Technology Center 1600 Group 1640 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communications and After Final communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov./. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tammy K. Field

Tammy K. Field
June 22, 2004

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